

Adverse Events Report [DATE]

Between our last report [DATE] and [DATE], there were [#] AEs among [#] unique participants that our technical team documented as adverse events (AEs). *Example Text: This higher number is due in part to the longer period of time between reports (8 months, compared with the usual 3-4 months) as study activities have slowly restarted during the COVID-19 pandemic. The events were expected, given our high-risk population. It should be mentioned that none of these events were thought to be caused or exacerbated by the participants' involvement in this study. Likewise, we did not feel that these events put anyone aside from the individual experiencing it at any greater risk. There have been no severe adverse events that have been reported to the IRB in this period.*

Date of Incident	Date of Report	Date of Enrollment	ID #	Study Group*	Incident Summary	Outcome
6/18/YR	6/29/YR	10/1/YR			ER visit for [INSERT]	Participant released from ER but refused to do follow-up forms with study staff
1/15/YR	1/15/YR	10/8/YR			During study visit, participant shared with study staff [INSERT]	Participant sent to treatment
4/13/YR	5/11/YR	3/23/YR			Participant sent to ER for [INSERT]	Participant in treatment
Not reported	1/22/YR	2/12/YR			During study visit, participant shared [INSERT]	Participant discharged home
Not reported	4/6/YR	10/8/YR			During study visit, participant shared they were hospitalized and went to the ER for [INSERT]	Participant discharged home

Between our last report [DATE] and [DATE], there were [#] AEs among [#] unique participants. These participants are in the following randomization groups:

Group	Number of Participants

Since enrollment began through [DATE], [#] participants have had adverse events. These participants are in the following randomization groups:

Group	Number of Participants